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EXAMINER

BRUSCA, JOHN S

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 20040401

Application Number: 09/313,292
Filing Date: May 13, 1999
Appellant(s): WILLIAMS ET AL.

James S. Keddie
Carol L. Francis
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11 December 2003 and the supplemental appeal brief filed 20 February 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 123-130 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because the specification states in Table 1A on page 94 that the insert in clone

number M00007118B:B04 of ATCC Deposit Number PTA-60 is identical to SEQ ID NO:972. Both SEQ ID NO: 272 and the insert in clone number M00007118B:B04 of ATCC Deposit Number PTA-60 are described in the specification. Since the rejection under 35 U.S.C. § 112, first paragraph for lack of written description concerns the lack of description for sequences larger than either SEQ ID NO:972 or the insert in clone number M00007118B:B04 of ATCC Deposit Number PTA-60, all claims are rejected for the same reason and the should stand or fall together.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 123-130 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is based on a lack of written description.

The specification discloses SEQ ID NO:972 which is less than full length cDNA as noted on page 45, lines 17-20. SEQ ID NO:972 meets the written description provisions of 35 USC

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112, first paragraph. However, claims 123-130 encompass full length cDNA comprising SEQ ID NO:972, genomic sequences that hybridize to SEQ ID NO:972, and vectors and host cells comprising full length cDNA comprising SEQ ID NO:972. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that

"applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:972, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

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An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

Accordingly, the specification does not provide a written description of the invention of claims 123-130.

(11) Response to Argument

The applicants state that full length cDNA is but one species encompassed by the claims. It should be noted that the claims read on a multitude of undescribed fragments of full length cDNA that are larger than SEQ ID NO:972. The number of undescribed species cannot be determined because the length of the corresponding full length cDNA is unknown. The claims also read on a multitude of fragments of genomic sequences that comprise SEQ ID NO:972. Therefore the claims read on a multitude of undescribed species.

The applicants refer to the declaration of Dr. Christopher Somerville in support of description of the claimed invention. However, the declaration of Dr. Somerville merely discusses prior art description of vector sequences that might flank the claimed sequences and methods of isolation of full length cDNA sequences, but fails to provide any evidence that the specification describes the sequence of the claimed full length cDNA, genomic sequences, or undisclosed fragments thereof that are claimed. Vectors are well known in the prior art and need not be described in the instant application. It is the open language applied to SEQ ID NO:972 that causes the rejection for lack of written description. For example, a claim drawn to a vector comprising an insert consisting of SEQ ID NO:972 would be allowable.

The applicants state that a skilled person could recognize whether a polynucleotide comprised the common structural feature of SEQ ID NO:972 by any of several methods of the art. However that is irrelevant to the question of whether the specification at the time of filing described polynucleotides comprising SEQ ID NO:972. What is relevant is whether one of skill in the art would recognize that the applicants had possession at the time of filing of a representative number of species of the claimed invention. Because a large number of species of the claimed genus of polynucleotides, vectors, and cells have sequences that are not fully described, one of skill in the art could not know that the applicants had possession of a representative number of species of the claimed genus at the time of filing of the instant application.

The applicants state that a skilled person at the time of filing of the instant application had a dramatically higher skill level than one at the time of filing of the applications that were subject to the court decisions discussed above. However the applicants fail to show how such increased skill level would allow one of skill in the art to understand that the applicants had possession at the time of filing of a claimed species such as full length cDNA corresponding to SEQ ID NO:972.

The applicants point to differences between the facts of the court decisions discussed above and the instant claims. The Office has interpreted the binding precedent of the above court decisions to require the instant rejection under 35 U.S.C. § 112, first paragraph for lack of written description.

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The applicants argue that if they were limited to closed language the commercial value of a patent issuing from the instant application would be severely reduced. While the applicant's protestation appears to be true, it is also irrelevant to the question of whether the claims are valid.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

John S. Brusca 2 April 2004

John S. Brusca

Primary Examiner

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jsb

April 2, 2004

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